



## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1239]

### **Certain Gabapentin Immunoassay Kits and Test Strips, Components Thereof, and Methods Therefor; Notice of Commission Determination to Issue a Limited Exclusion Order Against Defaulting Respondent; Termination of the Investigation**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to issue a limited exclusion order against Kappa City Biotech, SAS of Montlucon, France (“Kappa City”). The Commission has also determined to impose a bond equal to one hundred (100) percent of the entered value of the infringing products imported during the period of Presidential review. The investigation is hereby terminated.

**FOR FURTHER INFORMATION CONTACT:** Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email [EDIS3Help@usitc.gov](mailto:EDIS3Help@usitc.gov). General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** On January 25, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (“section 337”), based on a complaint filed by ARK Diagnostics, Inc. of Fremont, California (“ARK”). See 86 FR 6918-19. The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, sale for importation, or sale after importation into the United States of certain gabapentin immunoassay kits and test strips,

components thereof, and methods therefor by reason of infringement of certain claims of U.S. Patent Nos. 8,828,665 and 10,203,345. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation names fourteen respondents, including Kappa City; Healgen Scientific, LLC of Houston, Texas; 12PanelMedical, Inc. of Sarasota, Florida; Acro Biotech, Inc. of Rancho Cucamonga, California; AlcoPro, Inc. of Knoxville, Tennessee; American Screening, LLC of Shreveport, Louisiana; Chemtron Biotech Co., Ltd. of San Diego, California; Confirm Biosciences, Inc. of San Diego, California; Hangzhou All Test Biotech Co., Ltd. of Hangzhou, China; Mercedes Medical, LLC of Lakewood Ranch, Florida; TransMed Co., LLC of Alpharetta, Georgia; Transmetron, Inc. of Salt Lake City, Utah; Zhejiang Orient Gene Biotech Co., Ltd. of Huzhou, China; and Shanghai Chemtron Biotech Co., Ltd. of Shanghai, China (“Shanghai Chemtron”). *See id.* The complaint and notice of investigation were later amended to add two respondents, 12Panel Now, Inc. and Hospital Connect, Inc., both of Boynton Beach, Florida. Order No. 8 (March 9, 2021), *unreviewed by* 86 FR 16640-41 (March 30, 2021).

The Commission previously terminated six respondents based on consent orders. Order Nos. 11 and 12 (Mar. 31, 2021), *unreviewed by* Comm’n Notice (Apr. 15, 2021) (TransMed Co., LLC, 12PanelMedical, Inc., 12Panel Now, Inc., and Hospital Connect, Inc.); Order No. 14 (April 9, 2021), *unreviewed by* Comm’n Notice (Apr. 22, 2021) (Mercedes Medical, LLC); Order No. 15 (April 12, 2021), *unreviewed by* Comm’n Notice (May 12, 2021) (Transmetron Inc.). The Commission also previously terminated four respondents based on settlement agreements. Order No. 13 (Apr. 5, 2021), *unreviewed by* Comm’n Notice (Apr. 19, 2021) (Confirm Biosciences, Inc.); Order No. 17 (May 5, 2021), *unreviewed by* Comm’n Notice (May 18, 2021) (AlcoPro, Inc.); Order No. 18 (May 20, 2021), *unreviewed by* Comm’n Notice (June 21, 2021) (American Screening, LLC); Order No. 29 (Jan. 31, 2022), *unreviewed by* 87 FR 11096-98 (Feb. 28, 2022) (Shanghai Chemtron). The Commission also terminated five respondents based on partial withdrawal of the complaint. Order No. 20 (June 4, 2021),

*unreviewed by* Comm’n Notice (June 28, 2021) (Chemtron Biotech, Inc.); Order No. 21 (June 14, 2021), *unreviewed by* Comm’n Notice (July 1, 2021) (Hangzhou AllTest Biotech Co., Ltd.; Acro Biotech, Inc.; Zhejiang Orient Gene Biotech Co, Ltd.; Healgen Scientific, LLC).

On May 18, 2021, the Commission determined not to review an initial determination (Order No. 16) finding Kappa City in default. Order No. 16 (Apr. 30, 2021), *unreviewed by* Comm’n Notice (May 18, 2021).

On December 7, 2021, ARK filed a declaration seeking immediate entry of a limited exclusion order and cease and desist order against Kappa City.

On February 22, 2022, the Commission determined not to review an initial determination granting a motion to terminate Shanghai Chemtron based on settlement. See Order No. 29 (Jan. 31, 2022), *unreviewed by* 87 FR 11096-98 (Feb. 28, 2022). The Commission concurrently determined that ARK’s declaration was moot given the termination of the final remaining non-defaulting respondent in this investigation. 87 FR at 11097. The Commission also requested briefing on the issues of remedy, bonding, and the public interest. *Id.*

On March 8, 2022, ARK filed the sole response to the Commission’s request for briefing. No replies or other submissions were received.

Upon review of the record, including ARK’s submission, and in the absence of any response from Kappa City or from other interested persons or government agencies, the Commission has determined to issue a limited exclusion order against Kappa City pursuant to section 337(g)(1). The Commission has determined not to issue a cease and desist order against Kappa City, which is a foreign respondent. See, e.g., *In the Matter of Certain Powered Cover Plates*, Inv. No. 337-TA-1124, Comm’n Op. at 24-28 (July 10, 2020); *Certain Earpiece Devices and Components Thereof*, Inv. No. 337-TA- 1121, Comm’n Op. at 42-44 (Nov. 9, 2019); *Certain Electric Skin Care Devices, Brushes and Chargers Therefore, and Kits Containing the Same*, Inv. No. 337-TA-959, Comm’n Op. at 28-33 (Feb. 13, 2017). The Commission has determined that the public interest factors do not preclude issuance of the remedial order. The Commission

has further determined to set a bond in the amount of one hundred (100) percent of the entered value of the covered products imported during the period of Presidential review (19 U.S.C. 1337(j)). The Commission's order was delivered to the President and the United States Trade Representative on the day of its issuance. The investigation is hereby terminated.

Commissioners Schmidtlein and Karpel would issue both a limited exclusion order and a cease and desist order against Kappa City pursuant to section 337(g)(1) because all requirements of this provision are met. 19 U.S.C. 1337(g)(1)(A)-(E). Specifically, Kappa City was named in the complaint and was served the complaint and notice of investigation. *See* Order No. 16 (Apr. 30, 2021), *unreviewed by* Comm'n Notice (May 18, 2021). Kappa City failed to show good cause why it should not be held in default for failing to respond to the complaint and notice of investigation. *See id.* These findings satisfy subsections 337(g)(1)(A)-(D). ARK requested a limited exclusion order and a cease and desist order against Kappa City satisfying subsection 337(g)(1)(E). Given that subsections 337(g)(1)(A)-(E) are satisfied, the statute directs the Commission to issue the requested limited exclusion order and cease and desist order, subject to consideration of the public interest. Commissioners Schmidtlein and Karpel find that issuance of the requested relief would not adversely impact the public interest factors.

While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the complainant complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

The Commission vote for this determination took place on July 25, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 25, 2022.

**Katherine Hiner,**

*Acting Secretary to the Commission.*

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